

(PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Robert K. SCHULTZ et al.

Confirmation No.: 8899

Application No.: 10/820,817

Art Unit: 1615

Filed: April 9, 2004

Examiner: E. E. Silverman

For: SUSPENSION AEROSOL FORMULATIONS

# INFORMATION DISCLOSURE STATEMENT (SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

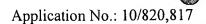
Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

### I. <u>LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION</u>

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

#### II. <u>COPIES</u>

	a.	Copies of cited U.S. patents and patent application publications are not included.
Copies	s of fore	ign patent documents and non-patent literature are included.
	b.	Some or all of the documents listed on the PTO-SB08 are not enclosed because
they w	vere cite	d in the International Search Report and copies should already be in the PTO file.
If copi	ies are n	eeded, please contact the undersigned.







© c. <u>REFERENCES PREVIOUSLY CITED OR SUBMITTED</u> - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in related <u>U.S. Application Nos. 09/362,696; 09/444,296; or 10/214,186</u>, or in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Application No. and U.S. Filing Date

08/455,280 filed May 31, 1995

07/878,039 filed May 4, 1992

07/809,791 filed December 18, 1991

07/810,401 filed December 18, 1991

#### III. CONCISE EXPLANATION OF THE RELEVANCE

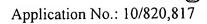
(check at least one box)

- a. <u>DOCUMENTS IN THE ENGLISH LANGUAGE</u> The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.
- b. <u>DOCUMENTS NOT IN THE ENGLISH LANGUAGE</u> A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:
- c. <u>ENGLISH LANGUAGE SEARCH REPORT</u> An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).
- d. OTHER The following additional information is provided for the Examiner's consideration. Each reference listed on the attached SB08, were cited in a related application, as noted above (see box II.c.), with the exception of B. K. Sidhu et al., J. Pharm. Pharmacol., 1993, 45: 597-600, which is first cited herein.





IV.	<u>FEES</u>	(check one box)
	a.	This Information Disclosure Statement is being filed concurrently with the filing
of a ne	w pater	at application; therefore, no fee is required.
	b.	This Information Disclosure Statement/is being filed concurrent with the filing of
a conti	nuation	-in-part, continuation, or divisional patent application; therefore, no fee is required.
	c.	This Information Disclosure Statement is being filed within three months of the
filing	date of	a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required.
(This s	ection i	s not to be used with RCE's.)
	d.	This Information Disclosure Statement is being filed within three months of the
date of	f entry o	f the national stage as set forth in § 1.491 in an international application (37 C.F.R.
§ 1.97	(b)(2)).	No fee or statement is required.
	e.	This Information Disclosure Statement is being filed concurrently with the filing
of a F	Request	for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or
statem	ent is re	quired.
	f.	This Information Disclosure Statement is being filed before the mailing date of a
first A	ction or	the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event
that a	first Off	ice Action on the merits has been issued, please consider this IDS under 37 C.F.R.
§ 1.97	(c) and	see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been
made,	charge	our deposit account for the fee as required by 37 C.F.R. § 1.17(p).
	g.	This Information Disclosure Statement is being filed before the mailing date of a
Final (	Office A	action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing
date of	f a Notic	te of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).
	$\boxtimes$	No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.
	or	
	☐ See	the statement below. No fee is required.

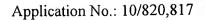




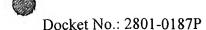
## V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check only one box)

	The und	ersigned he	reby states that:								
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30 days	s prior to	the filing o	f this IDS; or								
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	c.	No item of i	nformation conta	ined in the I	DS was	cited in	n a co	mmuni	cation	from	ıa
foreign	Patent (	Office in a	counterpart forei	gn applicati	on, and,	to the	know	ledge	of the	perso	on
signing	the cert	tification at	fter making reas	onable inqu	iry, no i	item of	f IDS	was k	nown	to ai	ny
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VI.	PAYME	ENT OF FE	ES (check one bo	x)							
	□ 1	The required	I fee is listed on t	he attached	Fee Trar	nsmitta	1.				
		No fee is red	quired.		•						







If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: November 21, 2005

Respectfully submitted,

Gerald M Murphy, Jr.

Registration No.: 28,977

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Attorney for Applicant

Attachment(s):

PTO-SB08
Documents

Foreign Search Report

Fee Fee

Other:

JUN 1.6 2006

PTO/SB/08a/b (07-05) Approved for use through 07/31/2006. OMB 0651-0031
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Complete if Known Substitute for form 1449A/B/P 10/820,817-Conf. #8899 **Application Number** INFORMATION DISCLOSURE Filing Date April 9, 2004 STATEMENT BY APPLICANT Robert K. SCHULTZ First Named Inventor 1615 Art Unit (Use as many sheets as necessary) Examiner Name E. E. Silverman 2801-0187P 7 Attorney Docket Number 1 of Sheet

			U.S. PA	TENT DOCUMENTS		David Oakimaa Linas 140
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( if known)	Publication Date MM-DD-YYYY	Name of Patente Applicant of Cited Do		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA*	US-5,145,684	09-08-1992	Liversidge et al.	<del> </del>	
		US-5,492,688	02-20-1996		<u> </u>	
		US-5,508,023	04-16-1996			
		US-5,776,433	07-07-1998			
	AE*	US-5,817,293	10-06-1998			
	AF*	US-5,833,950	11-10-1998			
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	AH*	US-5,922,306	07-13-1999	Akehurst et al.		
	AI*	US-6,006,745	12-28-1999			
	AJ*	US-6,013,245	01-11-2000			
	AK*	US-6,068,832	05-30-2000			
	AL*	US-6,200,549	03-30-2000	Akehurst et al.	***************************************	
	AM*	US-6,221,339	04-24-2001	Akehurst et al.		
		US-6,238,647	05-29-2001	Akehurst et al.	A-0-5	
		US-6,251,368		Akehurst et al.		
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	AV*	US-6,309,624		Akehurst et al.		
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		US-2,868,691		Porush et al.		
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		US-3,261,748	07-19-1966	Larsen et al.		
	AS1*	US-3,320,125	05-16-1967	Grim et al.		
Examine Signature					Date Considered	





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Complete if Known Substitute for form 1449A/B/PTO 10/820,817-Conf. #8899 Application Number April 9, 2004 INFORMATION DISCLOSURE Filing Date STATEMENT BY APPLICANT Robert K. SCHULTZ First Named Inventor 1615 Art Unit (Use as many sheets as necessary) Examiner Name E. E. Silverman 2801-0187P 7 Attorney Docket Number 2 of Sheet

			<del>,</del>	
AT1*	US-3,644,353		Lunts, Lawrence et al.	
AU1*	US-3,809,294		William Torgeson	
AV1*	US-3,897,779	08-05-1975		
AW1	US-4,044,126	08-23-1977	Cook et al.	
	US-4,129,603		Stephen L. Bell	
AY1*	US-4,174,295		Bargigia et al.	<u></u>
AZ1*	US-4,241,048	12-23-1980	Durbak et al.	
	US-4,311,863	01-19-1982	William H. Gumprecht	
AB2*	US-4,347,236	08-31-1982	Paavo Tanskanen	
AC2*	US-4,352,789	10-05-1982	Brown et al.	
AD2*	US-4,405,598	09-20-1983	Kenneth Brown	
AE2*	US-4,814,161	03-07-1989	Jinks et al.	
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AG2*	US-4,859,696		Kamiya et al.	
AH2*	US-4,940,171	07-10-1990		
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AJ2*	US-5,118,494	06-02-1992	Schultz et al.	
AK2*	US-5,126,123	06-30-1992	Johnson	
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AO2*	US-5,202,110	04-13-1993		
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AT2*	US-5,254,755	10-19-1993	Li et al.	
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AX2*	US-5,314,682	05-24-1994	Sweval et al.	
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	US-5,688,782	11-18-1997	Neale et al.	
	US-5,695,743		Purewal et al.	
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Date Examiner Considered Signature



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Substitute for form 1449A/B/PTO				Complete if Known		
Substitute for form 1445 Abre 10		Application Number	10/820,817-Conf. #8899			
INF	ORMATIC	ON DI	SCLOSURE	Filing Date	April 9, 2004	
STATEMENT BY APPLICANT				First Named Inventor	Robert K. SCHULTZ	
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(Use as many sheets as necessary)		Examiner Name	E. E. Silverman			
boot	3	of	7	Attorney Docket Number	2801-0187P	

AO3* I	US-5,720,940	02-24-1998	Purewal et al.	
AP3* I	US-5,736,124	04-07-1998	Akehurst et al.	
AQ3*	US-5,744,123	04-28-1998	Akehurst et al.	
 AR3*	US-5,766,573	06-16-1998	Purewal et al.	
 AS3*	US-5,776,432	07-07-1998	Schultz et al.	
 AT3*	US-5,776,434	07-07-1998	Purewal et al.	

		FOREIG	GN PATENT D	OCUMENTS		
		Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,	
Examiner Initials*	Cite No. <sup>1</sup>	Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T⁰
	BA	CA-2,075,058-A2	01-31-1991			<u> </u>
	BB	GB-91/26405.1	12-12-1991			_
	BC	GB-91/26378.0	12-12-1991			L
	BD	GB-92/02522.0	02-06-1992			上
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	BG	WO-98/52542-A1	11-26-1998			
	ВН	EP-0 518 601-A1	12-16-1992			_
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	BJ	EP-0 656 206-A1	06-07-1995			
	ВК	EP-0 656 207-A1	06-07-1995			L
	BL	EP-0 518 601	12-16-1992			_
	ВМ	JP-52-80282-A1	07-05-1977		,	
	BN	SE-437 766	03-18-1985			
	во	EP-0 365 119-A2	04-25-1990			
	BP	GB-2 235 627-A	03-13-1991			
	BQ	CA-2,062,854-A1	09-15-1992	_		
	BR	WO-92/00062-A1	01-09-1992			
	BS	WO-92/06675-A1	04-30-1992			
	вт	JP-60-227805-A	11-13-1985			
	BU	GB-2 001 334-A	01-31-1979			
	BV	WO-92/22286-A1	12-23-1992			
	BW	WO-93/05765-A1	04-01-1993			Γ
	BX	DE-27 03 119	08-04-1977			
	BY	DE-27 37 132	02-23-1978			П
-	BZ	DK-134923	02/1977			
	BA1	EP-0 039 369-A1	11/1981			
	BB1	EP-0 379 793-B1	01/1990			
	BC1	EP-0 372 777	06/1990			Π
	BD1	EP-0 384 371-A1	08/1990			
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	BL1	WO-90/11754	10/1990			

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Cub	estitute for form 1449A/B/PT	0		Complete if Known			
Sub	Siliule for form 1449A/B/P1	0		Application Number	10/820,817-Conf. #8899		
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	TATEMENT			First Named Inventor	Robert K. SCHULTZ		
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	(Use as many sh	eets as	necessary)	Examiner Name	E. E. Silverman		
Sheet	4	of	7	Attorney Docket Number	2801-0187P		

BM1	WO-91/04011	04/1991	 	 $\Box$
BN1	WO-91/11173	08/1991	 0	
BO1	WO-91/11495	08/1991		 $\square$
BP1	WO-91/11496	08/1991	 	
BQ1	WO-91/14422	10/1991		
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BA2	WO-93/11745	06/1993	 	
BB2	WO-93/11747	06/1993		
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BD2	GB-2 076 422	12-02-1981		
BE2	GB-1 429 184	03-24-1976	 	
BF2	DE-30 18 550	12-11-1980		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. \(^1\) Applicant's unique citation designation number (optional). \(^2\) See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. \(^3\) Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \(^4\) For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \(^5\) Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \(^6\) Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	· 1 magazine loumai senai symposiumi calalog, etc.), date, page(s), volume-issue number(s), public				
	CA	Byron, 1990, Respiratory Drug Del. CRC Press, Boaca Raton, FL, pp. 1-267			
	СВ	Graepel & Alexander, 1991, J. of Aerosol Med. 4(3):193-200			
	CC	Byron, 1990, Respiratory Drug Del. CRC Press, Boca Raton, FLA, pp. 1-267.			
	CD	Fassberg et al., 1991, U.S. Patent Application No. 07/712,789, filed 10 June 1991.			
	CE	Fassberg et al., 1992, U.S. Patent Application No. 08/157,188, filed as application no. PCT/US92/04618, filed 08 June 1992.			
	CF	Graepel & Alexander, 1991, "CFC Replacements: Safety Testing, Approval for Use in Metered Dose Inhalers", <i>J. of Aerosol Medicine</i> <b>4(3):193-200</b> .			
	CG	Morck, H., 1990, "EC Commission: CFC Ban in 1997", <i>Pharmazeutische Zeitung</i> 135(9):502-503. English Translation Provided.			
	СН	Spauchur, H.O., 1988, "HFC 134a as a Substitute Refrigerant for CFC 12", Rev. Int. Froid 11:389-392.			
	CI	1987, "Fluorocarbon/Ozone Alternative to Fully Halogenated Chlorofluorocarbons: The Du Pont Development Program", Du Pont Update, pp. 1-3			
	CJ	1988, "ICI Caution on CFC 22", Chemistry & Industry, Mar. 7, p. 132			
	СК	1988, "The Quest for 'Ozone Friendly' Gases", Financial Times, Nov. 11, p. 10.			
	CL	1990, "Hoechst to Replace CFCs", Brochure, Boescht um Ersatz von FCKW, September. English Translation Provided.			

Examiner	Date	
Signature	Considered	
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Substitute for form 1449A/B/PTO		Complete if Known			
Sub	Substitute for form 1445/2011 10			Application Number	10/820,817-Conf. #8899
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	April 9, 2004
				First Named Inventor	Robert K. SCHULTZ
Ū	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			Art Unit	1615
	(Use as many sheets as necessary)			Examiner Name	E. E. Silverman
Sheet	5	of	7	Attorney Docket Number	2801-0187P

	СМ	1992, "CFC-Free Aerosols - The Final Hurdle", Manufacturing Chemist 63:22-23.
	CN	Fassberg et al., 1991, U.S. Patent Application No. 07/712,791, filed as PCT/US92/04619, 08
	10	June 1992, now abandoned.
	со	Fassberg et al., 1993, U.S. Patent Application No. 08/157,182, filed 09 December 1993.
	CP	Keller, M., "Alternatives to CFC containing dosing aerosols," Maritim Hotel Cologne, Seminar
	0'	538 of the Working Party for Pharmaceutical Process Technology, March 1991
	ca	Hoescht: Development of alternatives for fully halogenated CFC is of highest importance,
	04	Hoescht Press Information, October 1989
	CR	U.S. Application No. 08/455,490 as filed on May 31, 1995, and a copy of the pending claims.
	cs	U.S. Application No. 08/455,874 as filed on May 31, 1995, and a copy of the pending claims.
	CT	Letter to European Patent Office, dated Aug. 10, 1995, in corresponding European Application
	.	93901414.8.
	CU	Letter to European Patent Office, dated Nov. 17, 1997, in Opposition to EP 553298.
	CV	Expert Report of Dr. John J. Sciarra in U.K. Patents Court, Chancery Division, Revocation
		Proceedings, CH 1997-M-No. 3722/3766, regarding European Patent 0 617 610.
	cw	Pumfrey, J., United Kingdom Patent Court decision, dated Jul. 28, 1998, in the High Court of
i		Justice, Chancery Division, Patent Court, combined cases CH 1997 M No. 3766 and CH 1997
		M No. 3722 (re European Patent No. 0 617 610).
	CX	Jacob J., United Kingdom Patents Court decision, dated Jun. 30, 1997, in the High Court of
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	CZ	Sanders, Paul A. PhD. Handbook of Aerosol Technology, 2.sup.nd Edition, 1979 (New York,
		New York: Van Nostrand Reinhold Company), p 30, 32, 33, 166, 167, 232, 233, 400, 401, 402.
	CA1	Dalby et al., "CFC Propellant Substitution: P-134a as a Potential Replacement for PL-12 in
		MDIs", Pharmaceutical Technology, Mar. 1990.
	CB1	Research Disclosure 16265, Oct. 1977.
	CC1	Research Disclosure 30161, May 1989.
	CD1	Oberholz, Frankfuter Allgemenine Zeitung, Oct. 1989, vol. 25, No. 207, p. 7.
	CE1	Dalby et al., Pharmaceutical Technology, Mar. 1990, vol. 14, No. 3, pp. `.
	CF1	Amzacort carton, William H. Rorer, Inc. Fort Washington, Pennsylvania, USA 19034, 1986.
	CG1	Kemper et al., Pharmaceutical Journal, Sep. 29, 1990, vol. 245, pp. 428-429.
	CH1	The Theory and Practice of Industrial Pharmacy, 2.sup.nd Ed. 1976 (Philadelphia PA: Lea and
	1	Febiger) pp. 270 and 276-278.
	CI1	Handbook of Aerosol Technology, 2.sup.nd Edition, 1979 (New York, New York: Van Nostrand
1		Reinhold Company), pp. 30, 32, 33, 166, 167, 232-233.
	CJ1	Hagers Handbook of Pharmaceutical Practice, 1971, pp. 342-354 (Berlin: Springer-Veriag).
	CK1	Transcript of Judgment by Mr. Justice Pumfrey.
	CL1	Oberholz, 1989, Frankfuter Allgemenine Zeitung, 25:207:7.
	CM1	Dalby et al., 1990, Pharmaceutical Technology, 14:3:26-33.
	CN1	1990, Pharmaceutical Journal, (Sep. 29) 245:428-429.
	CO1	1976, The Theory and Practice of Industrial Pharmacy, 2.sup.nd Ed., (Philadelphia, PA, Lea
		and Febiger), pp. 270 and 276-678.
	CP1	1979, Handbook of Aerosol Technology, 2.sup.nd Ed., (New York, New York: Van Nostrand
		Reinhold Company), pp. 30, 32, 33, 166, 167, 232-233.
	CQ1	U.S. Senate Hearings, May 12-14, 1987, 343-347, 437 (U.S. Government Printing Office,
		Washington, D.C., 1987), CIS: 1987-S321-26.
	CR1	1971, Hagers Handbook of Pharmaceutical Practice, pp. 342-354 (Berlin: Springer-Veriag).

Examiner	Date	
Signature	Considered	





PTO/SB/08a/b (07-05)

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Substitute for form 1449A/B/PTO				Complete if Known		
Su	Substitute tot totti 14442/DE 10			Application Number	10/820,817-Conf. #8899	
H	NFORMATIC	N DI	SCLOSURE	Filing Date	April 9, 2004	
	STATEMENT BY APPLICANT (Use as many sheets as necessary)			First Named Inventor	Robert K. SCHULTZ	
•				Art Unit	1615	
				Examiner Name	E. E. Silverman	
Sheet	6	of	7	Attorney Docket Number	2801-0187P	

_	CS1	Genarro, A. R., 1985, Remington's Pharmaceutical Sciences, 17th Ed., Mack Pub. Co., pp. 1670-1677.
	CT1	"CFC-Free AerosolsThe Final Hurdle", Manufacturing Chemist, 63(7):22-23, 1992.
	CU1	Kontny et al., "Issues Surrounding MDI Formulation Development with Non-CFC Propellants", Journal of Aerosol Medicine, 4(3):181-187, 1991.
	CV1	Moren, F., "Chlorofluorocarbons (CFCs) and Their Replacement", The Regulatory Affairs Journal, Jun. 1991, pp. 385-389.
	CW1	Dalby, R., "Special Considerations in the Formulation of Suspension Type Metered Dose Inhalers", Aerosol Age, pp. 22-24, 26-28, 34, and 89, Oct. 1990.
	CX1	Martindale: The Extra Pharmacopoeia. 28.sup.th Edition. Edited by James E.F. Reynolds, Assistant Editor Anne B. Prasad. The Pharmaceutical Press: London, 1982. Entry No. 1068-t.
	CY1	The Merck Index (Budavari, Susan, Editor, Merck & Co., Inc. U.S.A. 1989).
	CZ1	J. A. Ranucci et al., "Controlled Flocculation in Metered'Dose Aerosol Suspensions" Pharmaceutical Technology, pp. 69-74, Apr. 1990.
	CA2	Martindale: The Extra Pharmacopoeia. 28.sup.th Edition. Edited by James E.F. Reynolds, Assistant Editor Anne B. Prasad. The Pharmaceutical Press: London, 1982. Entry No. 1068-t.
	CB2	Hammerbeck et al., Inflammation, 24:4:317-329 (2000)
	CC2	Sidhu et al., J. Pharm. Pharmacol., 1993, 45: 597-600

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.